REMARKS

After entry of this amendment, claims 25, 27, 29-32, and 34-54 will be pending for the Examiner's review and consideration. The Office Action dated May 21, 2004 has been carefully considered. Claims 25, 27, 29-32, 34-39, and 41 have been amended without prejudice. Claims 28 and 33 have been canceled without prejudice. Claims 1-24 and 26 were previously canceled. Claim 54 has been added. No new matter has been added. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated May 21, 2004, the Examiner:

- objected to claims 27-39 for being dependent upon a canceled claim;
- rejected claims 25, 27, 29-32, 32-44, and 46-51 under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,200,347 to Anderson *et al.* ("Anderson"); and
- rejected claims 28, 33, 45, and 52-53 under 35 U.S.C. § 103(a) as being unpatentable in view of Anderson.

Dependent claims 27-39

Dependent claims 27-39 were objected to for being dependent upon a canceled claim. In response thereto, dependent claims 27-39 have been amended to depend from independent claim 25. Withdrawal of this rejection and allowance of claims 27-39 is respectfully requested.

Independent Claim 25

Independent claim 25 was rejected under 35 U.S.C. § 102(e) as being anticipated by Anderson. Independent claim 25 has been amended to make explicit what was already implicit and thus no estoppel effort should be given. Specifically, independent claim 25 has been amended to recite, *inter alia*, an implant comprising a body with first and second ends and a plurality of through-holes extending between the ends; a first and second cortical end cap disposed on each end of the body, at least one of the end caps comprising a height and a plurality of receiving regions having a depth and a bearing surface at an end therein; and a plurality of cortical struts wherein the depth of the receiving regions is less than the height of

PAGE 7/13 * RCVD AT 9/21/2004 1:45:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:+2127557306 * DURATION (mm-ss):04-48

the end cap so that the receiving regions do not extend completely through the end cap; and wherein each cortical strut is disposed in one of the through holes of the body and mates in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface. There is absolutely no disclosure, teaching, or suggestion in Anderson of an implant comprising a first and second cortical end cap wherein at least one of the end caps has a height and a plurality of receiving regions having a depth and a bearing surface at an end therein so that the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface.

Rather, Anderson discloses forming a composite bone graft from a first cortical plank 70, a cancellous plank 73, and a second cortical plank 70. The planks are assembled side by side so that holes 5 are drilled completely through the composite bone graft and pins 7 are inserted therethrough to couple the planks in their side by side relationship. Thus, Anderson does not disclose, teach, or suggest an implant comprising a first and second cortical end cap wherein at least one of the end caps has a height and a plurality of receiving regions having a depth and a bearing surface at an end therein so that the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface.

Thus, it is respectfully submitted, that Anderson does not disclose, teach, or suggest an implant comprising all of the limitations of independent claim 25. It is respectfully submitted that independent claim 25 is allowable over the cited prior art. Allowance of independent claim 25 is respectfully requested.

Moreover, to expedite prosecution of the present invention, the Applicant respectfully submits that contrary to the Examiner's statement that "[a]t the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to [include] ... a recess region in the cortical cap that does not extend completely through the end cap, Anderson does not render obvious independent claim 25. Specifically, it is respectfully submitted, that the Examiner's reasoning that providing a recess region which does not extend completely through the end cap would be obvious in view of Anderson is impermissible hindsight reconstruction and contrary to the teaching of Anderson.

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PAGE 8/13 * RCVD AT 9/21/2004 1:45:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:+2127557306 * DURATION (mm-ss):04-48

In order to establish a prima facie case of obviousness, the Examiner bears the burden of establishing three basic criteria. First, the Examiner must show that there was some suggestion or motivation, either in the references themselves or in the knowledge generally available to one skilled in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all of the claim limitations. *See* MPEP § 2142; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. Therefore, making a legal determination of obviousness does not mean that one can "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention." *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 858 F.2d 878, 8 USPQ2d 1468 (Fed. Cir. 1988). Rather, the Examiner must show, not that each element existed in the prior art, but that some teaching or suggestion in the references made obvious the invention as a whole. *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990).

As previously stated, it is respectfully submitted that Anderson does not disclose each and every element of the claimed invention. Specifically, Anderson does not disclose, teach or suggest an implant comprising a first and second cortical end cap wherein at least one of the end caps has a height and a plurality of receiving regions having a depth and a bearing surface at an end therein so that the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface.

Furthermore, it is respectfully submitted that the Examiner has not satisfied the burden of proving that there was some suggestion or motivation to modify Anderson to include a first and second cortical end cap wherein at least one of the end caps has a height and a plurality of receiving regions having a depth and a bearing surface at an end therein so that the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface. Rather, as previously described,

PAGE 9/13 * RCVD AT 9/21/2004 1:45:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:+2127557306 * DURATION (mm-ss):04-48

Anderson discloses forming a composite bone graft from a first cortical plank 70, a cancellous plank 73, and a second cortical plank 70. The planks are assembled side by side so that holes 5 are drilled completely through the composite bone graft and pins 7 are inserted therethrough to couple the planks in their side by side relationship. There is absolutely no suggestion or motivation to modify Anderson to include a first and second cortical end cap wherein at least one of the end caps has a height and a plurality of receiving regions having a depth and a bearing surface at an end therein so that the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface.

Furthermore, it is respectfully submitted that there was no suggestion or motivation within the knowledge generally available to one skilled in the art at the time of filing this application to modify the implant of Anderson to include receiving regions wherein the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface.

In fact, it is respectfully submitted that there is absolutely no reason for one of ordinary skill in the art to modify Anderson to include receiving regions wherein the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface. This is because Anderson, in each and every embodiment which includes a cancellous plank sandwiched between a pair of cortical planks teaches that the pins 7 are inserted in order to hold the composite implant together. That is, in each embodiment comprising a cancellous body sandwiched between cortical planks, the pins are inserted so that in use, *i.e.*, when the implant is inserted between adjacent verebral, the pins extend parallel to the vertebral endplates.

This is substantially different from the implant of independent claim 25 which incorporates cortical struts that in use, *i.e.*, when the implant is inserted between adjacent verebral, extend perpendicular in-between the vertebral endplates so that the cortical struts can received and transfer load. Therefore, it is respectfully submitted, that one of ordinary skill in the art would not from the disclosure of Anderson, modify the implant of Anderson to

PAGE 10/13 * RCVD AT 9/21/2004 1:45:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:+2127557306 * DURATION (mm-ss):04-48

include receiving regions wherein the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface.

Rather, it is respectfully submitted, that the Applicant through his own effort and expense derived the device as claimed in independent claim 25. It is respectfully submitted that without the benefit of the Applicant's disclosure, it would not be obvious for one of ordinary skill in the art to redesign Anderson to include receiving regions wherein the depth of the receiving regions is less than the height of the end cap so that the receiving regions do not extend completely through the end cap thus enabling the cortical strut to mate in one of the receiving regions of the cap so that at least a portion of the struts bear against at least a portion of the bearing surface. One cannot simply use the Applicant's disclosure as a blueprint to pick and choose among the individual elements of assorted prior art references in order to combine the right references in the right way to achieve the Applicant's claimed invention. *Grain Processing Corp. v. American Maize-Products Corp.* 840 F.2d 902 (Fed. Cir. 1988). Thus, it is respectfully submitted that independent claim 25 is allowable over the cited prior art. Withdrawal of this rejection and allowance of claim 25 is respectfully requested.

Dependent claims 27, 29-32, and 34-40 all ultimately depend from independent claim 25, thus, it is respectfully submitted that these claims are equally allowable. Allowance of claims 27, 29-32, and 34-40 is therefore respectfully requested.

Independent Claim 41

Independent claim 41 was rejected under 35 U.S.C. § 102(e) as being anticipated by Anderson. Independent claim 41 has been amended to make explicit what was already implicit and thus no estoppel effort should be given. Specifically, independent claim 41 has been amended to recite, *inter alia*, an implant comprising a first cortical end cap having a top surface for engaging a vertebral body, a bottom surface and a receiving region disposed therebetween; a second cortical end cap having a top surface for engaging a vertebral body, a bottom surface, and a receiving region disposed therebetween; a cancellous body having a first end for engaging the bottom surface of the first cortical end cap, a second end for engaging the bottom surface of the second cortical end cap, and at least one through-hole extending therebetween; at least one cortical strut disposed in the at least one through hole

PAGE 11/13 * RCVD AT 9/21/2004 1:45:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:+2127557306 * DURATION (mm-ss):04-48

formed in the body and in the at least one receiving region formed in the first and second end caps; wherein the first and second end of the cancellous body does not engage the vertebral body; and wherein the end caps are sized and dimensioned to serve as load-distributing members and the at least one cortical strut is sized and configured to serve as a load-bearing member. There is absolutely no disclosure, teaching, or suggestion in Anderson of an implant comprising a first cortical end cap having a top surface for engaging a vertebral body, a second cortical end cap having a top surface for engaging a vertebral body, and a cancellous body having a first end for engaging a bottom surface of the first cortical end cap, a second end for engaging a bottom surface of the second cortical end cap, wherein the first and second ends of the cancellous body do not engage the vertebral body.

Rather, Anderson discloses forming a composite bone graft from a first cortical plank 70, a cancellous plank 73, and a second cortical plank 70. The planks are assembled side by side so that holes 5 are drilled completely through the composite bone graft and pins 7 are inserted therethrough to couple the planks in their side by side relationship. That is, each and every embodiment of the Anderson patent which discloses a composite bone graft formed from a cancellous plank disposed between cortical planks (see, for example, FIGs. 1, 2, 6-10, 11b, 12, 13a, 27, 28, 30, 31) is designed so that at least a portion of the cancellous plank and at least a portion of the cortical planks directly engage the patient's bone. Thus, both the cancellous and the cortical planks of the Anderson patent contact the vertebral endplates of the adjacent vertebral bodies. Thus, there is no disclosure, suggestion, or teaching in Anderson of an implant comprising a first cortical end cap having a top surface for engaging a vertebral body, a second cortical end cap having a top surface for engaging a vertebral body, and a cancellous body having a first end for engaging a bottom surface of the first cortical end cap, a second end for engaging a bottom surface of the second cortical end cap, wherein the first and second ends of the cancellous body do not engage the vertebral body. Thus, it is respectfully submitted, that Anderson does not disclose, teach, or suggest an implant comprising all of the limitations of independent claim 41. It is respectfully submitted that independent claim 41 is allowable over the cited prior art. Allowance of independent claim 41 is respectfully requested.

Dependent claims 42-53 all ultimately depend from independent claim 41, and thus, it is respectfully submitted that these claims are equally allowable. Allowance of claims 42-53 is therefore respectfully requested.

PAGE 12/13 * RCVD AT 9/21/2004 1:45:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:+2127557306 * DURATION (mm-ss):04-48

Independent Claim 54

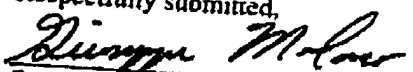
Newly added independent claim 54 recites, *inter alia*, an implant comprising a first cortical end cap having a top surface for engaging a vertebral body, a bottom surface, a height dimension extending between the top surface and the bottom surface and at least one recess disposed therein; a second cortical end cap having a top surface for engaging a vertebral body, a bottom surface, a height dimension extending between the top surface and the bottom surface and at least one recess disposed therein; a cancellous body having a first end for engaging the bottom surface of the first cortical end cap, a second end for engaging the bottom surface of the second cortical end cap, and at least one through-hole extending thereberween; at least one cortical strut disposed in the at least one through hole formed in the body and in the at least one recess formed in the first and second end caps; wherein the first and second ends of the cancellous body do not engage the vertebral body; and wherein at least one of the recesses formed in either of the first or second end cap has a depth less than the height of the end cap so that the recess does not extend completely through the end cap.

It is respectfully submitted that for at least the reasons previously described in connection with independent claims 25 and 41, Anderson does not disclose, teach, or suggest all of the limitations of independent claim 54. It is respectfully submitted that independent claim 54 is allowable over the cited prior art. Allowance of independent claim 54 is respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 25, 27, 29-32, and 34-54 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-326-7883, if a telephone call could help resolve any remaining issues.

Date: September 21, 2004

Respectfully submitted,



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PAGE 13/13 * RCVD AT 9/21/2004 1:45:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:+2127557306 * DURATION (mm-ss):04-48